DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2839. Adulteration of thiamine hydrochloride injection, sodium salicylate and iodide with colchicine ampuls, and physiological salt solution. U. S. v. Gotham Pharmaceutical Co., Inc. Plea of guilty. Fine, $1,500. (F. D. C. No. 24257. Sample Nos. 1001K, 66337–H, 87813–H.)

INFORMATION FILED: October 19, 1948, Eastern District of New York, against Gotham Pharmaceutical Co., Inc., Brooklyn, N. Y.

ALLEGED SHIPMENT: On or about June 9 and 12 and August 13, 1947, from the State of New York into the States of Florida, Pennsylvania, and New Jersey.

NATURE OF CHARGE: *Thiamine hydrochloride injection* and *physiological salt solution.* Adulteration, Section 501 (b), the articles purported to be, and were represented as, drugs the names of which, "Thiamine Hydrochloride Injection" and "Physiological Salt Solution," respectively, are recognized in the United States Pharmacopoeia; and their quality and purity fell below the official standards. The standards provide that such articles must conform to the requirements for injections prescribed in the Pharmacopoeia, and the articles failed to meet those requirements for injection since they were not substantially free of undissolved material which could be detected when tested in accordance with the prescribed method; and the difference in quality and purity of the articles from the standards was not plainly stated, or stated at all, in their labeling.

Sodium salicylate and iodide with colchicine ampuls. Adulteration, Section 501 (b), the article purported to be, and was represented as, "Sodium Salicylate and Iodide with Colchicine Ampuls," the name of which is recognized in the National Formulary; and its quality and purity fell below the official standard. The standard provides that "Sodium Salicylate and Iodide with Colchicine Ampuls" must conform to the requirements for ampuls prescribed in the Formulary, whereas the article failed to meet the requirements for ampuls so prescribed since it was not substantially free from undissolved material which could be detected when tested in accordance with the prescribed method; and its difference in quality and purity from the standard was not plainly stated, or stated at all, on its label.

DISPOSITION: February 24, 1949. A plea of guilty having been entered, the court imposed a fine of $1,500.

2840. Adulteration and misbranding of estrogenic substances. U. S. v. 6 Vials * * *. (F. D. C. No. 27162. Sample Nos. 56162–K, 56176–K.)

LIBEL FILED: On or about April 27, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about January 5, 1949, by Rare Chemicals, Inc., from Harrison, N. J.

PRODUCT: 6 10-cc. vials of *estrogenic substances* at New York, N. Y.

LABEL, IN PART: (Carton) "Estrogenic Substances Rare In Sesame Oil Natural estrogenic substances in sesame oil with 3% benzyl alcohol 1 cc – 50,000 I. U. Natural Estrogenic Substances."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article fell below that which it was represented to possess, namely, an amount of natural estrogenic substances equivalent to 50,000 International Units of estrone activity per cubic centimeter.

Misbranding, Section 502 (a), the label statement "1 cc – 50,000 I. U. Natural estrogenic substances consisting predominantly of estrone" was false and misleading as applied to the article, which contained an amount of natural estrogenic substances equivalent to not more than 37,500 International Units of estrone activity per cubic centimeter.

DISPOSITION: May 18, 1949. Default decree of condemnation and destruction.

2841. Adulteration and misbranding of theobromine, calcium lactate, nitroglycerin tablets. U. S. v. 1 Drum * * *. (F. D. C. No. 27153. Sample No. 56192–K.)

LIBEL FILED: On or about April 27, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about November 19, 1946, from New Brunswick, N. J.

PRODUCT: 1 drum containing approximately 18,500 *theobromine, calcium lactate, nitroglycerin tablets* at New York, N. Y. Analysis of the product failed to reveal the presence of nitroglycerin.

LABEL, IN PART: (Drum) "Theobromine, Calcium Lactate, Nitroglycerin Tablets."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "0.0002 gms. Nitroglycerin."

Misbranding, Section 502 (a), the label statement "0.0002 gms. Nitroglycerin" was false and misleading. The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 18, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

2842. Misbranding of Tri-Estrin Tablets. U. S. v. Endocrine Co. and Herbert G. Brower. Pleas of nolo contendere. Fine of $200 against company and $1 against individual. (F. D. C. No. 24275. Sample No. 74627–H.)

INFORMATION FILED: July 12, 1948, District of New Jersey, against the Endocrine Co., a corporation, Union City, N. J., and Herbert G. Brower, president and treasurer of the corporation.

ALLEGED SHIPMENT: On or about February 4, 1947, from the State of New Jersey into the State of Massachusetts.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Estrogenic substance derived from gravid mare's urine, containing principally estrone and estradiol" was false and misleading. The statement represented and suggested that the estrogenic material present in the article consisted of estrogenic substance as it naturally occurs in, and is extracted from, gravid mare's urine, whereas the estrogenic material present in the article did not

*See also Nos. 2833, 2834, 2840, 2841.